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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,674	02/17/2006	Kristine G. Koski	JA 14647-45	4493

1059 7590 05/11/2009

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EXAMINER	
ROY, BAISAKHI	
ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
05/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,674	KOSKI ET AL.	
	Examiner	Art Unit	
	BAISAKHI ROY	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 3-19, 22-31, and 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6690958) in view of Rosenfeld et al. (7191068).

Walker et al. disclose an optical probe system and method for analyzing body fluids including amniotic fluid where the probe head or optical coupler is positioned against the mother's skin with respect to the amniotic sac and obtaining ultrasound images (col. 15 lines 50-col. 6 line 6 lines 35-50). Walker et al. teach directing the optical source through the abdominal wall, amniotic fluid, and the abdominal wall layers (col. 16 lines 35-67). Walker et al. do not explicitly teach measuring the biochemical markers in the amniotic fluid.

In the same field of endeavor Rosenfeld et al. disclose a non-invasive system and method for early diagnosis, prognosis, and monitoring or measuring of pathological fetal/maternal conditions by analysis of biological fluids such as amniotic fluid (col. 2 lines 60-col. 3 line10). Rosenfeld et al. teach analyzing cervix conditions and therefore also includes measuring cervical fluid conditions (col. 17 lines 17-25 lines 47-55). The process involves providing a device such as a mass spectrometer (col. 9 lines 52-65) for measuring one or more selected biological markers in the amniotic fluid to diagnose

various conditions or abnormalities or intra-amniotic infections (col. 11 lines 44-61). The spectrometer is arranged with respect to the amniotic sac to measure amniotic fluid in situ without insertion of any instrument into the amniotic sac, using said device to acquire measurement data, and processing the measurement data to obtain a value for the selected biological markers in the amniotic fluid (see example 1).

Therefore by measuring the markers in the amniotic fluid and monitoring the flow of fluid through the abdominal wall provides information related to intrauterine conditions (col. 24 lines 63-67). For human studies Rosenfeld et al. teach measuring various markers in amniotic fluid and ultrasound imaging, and amniocentesis is performed during the first trimester (col. 17 lines 36-61). It is well known to conduct measurements and monitor the pregnancy period effectively during each of the three trimesters.

The marker may also comprise glucose to control gestational diabetes (col. 11 lines 27-32). The marker comprises the insulin-like growth factor (IGF-BP1) (col. 27 lines 7-29). The amniotic fluid data is used to obtain a value regarding the risk of the offspring being born with high or low birth weight (col. 10 lines 45-47). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Rosenfeld et al. to modify Walker et al. such that amniotic fluid markers may be measured effectively.

3. Claims 2, 20, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et in view Rosenfeld et al., as applied to claims 1-31 above, and further in view of Khoury et al. (6618138).

Walker et al. and Rosenfeld et al. teach the use of a spectrometer for measuring the markers but do not teach the use of a Raman spectrometer. In the same field of endeavor Khoury et al. disclose a system and method for analysis of biological fluids including amniotic fluids (col. 2 lines 16-19). Khoury et al. also teach the use of a Raman spectrometer (col. 2 lines 46-49). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Khoury et al. to modify Walker and Rosenfeld et al. such that the markers in the amniotic fluid flowing through the abdominal wall are analyzed in a fast and efficient manner for the recognition of materials or compounds that are indicative of birth disorders.

4. Claims 21 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. Rosenfeld et al., as applied to claims 16-33 above, and further in view of Ebbels et al. (6683455).

Walker et al. and Rosenfeld et al. teach the use of spectroscopy to analyze the markers in amniotic fluid but do not teach the use of magnetic resonance spectroscopy. In the same field of endeavor Ebbels et al. disclose a system and method for analyzing fluid samples including amniotic fluid using spectroscopy such as magnetic resonance spectroscopy (col. 12 lines 62-col. 13 line 9, lines 58-64). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Ebbels et al. to modify Walker et al. and Rosenfeld et al. such that significant markers/analytes found in amniotic fluid may be measured for effective diagnosis of birth disorders or abnormalities.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR
/Baisakhi Roy/
Examiner, Art Unit 3737